GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:664
ANSWERED ON:18.11.2016
Drug Trials
Patil Shri A.T. (Nana)

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Drug Controller General of India has proposed to waive local trials of drugs meant for treating certain types of life threatening ailments and rare diseases;

(b) if so, the details thereof along with the reasons therefor; and

(c) the steps taken by the Government for post marketing surveillance of such drugs in order to monitor their safety and efficacy?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): In accordance with the Drugs and Cosmetics Rules, 1945, the toxicological and clinical data requirements for drugs indicated for life threatening/serious diseases or diseases of special relevance to the Indian health scenario can be abbreviated, deferred or omitted as deemed appropriate by the Licensing Authority.

(c): In addition to the post marketing surveillance as part of the clinical trial process, a comprehensive Pharmacovigilance Programme of India has been rolled out for monitoring the safety of the marketed drugs in the country.